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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,640	08/20/2001	Eliczer Masliah	6627-PA1071	6686
25225 7590 01/29/2007 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			EXAMINER FALK, ANNE MARIE	
			ART UNIT	PAPER NUMBER
			1632	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/29/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/933,640

Applicant(s)

MASLIAH ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 37 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36, 38 and 40-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/27/06
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

The amendment filed November 6, 2006 (hereinafter referred to as "the response") has been entered. Claims 1, 27, and 37-40 have been amended. Claim 43 has been newly added.

Accordingly, Claims 1-43 are pending in the instant application.

The elected invention is drawn to a transgenic mouse comprising, integrated into its genome, a gene encoding human amyloid precursor protein and a gene encoding human α -synuclein.

Claims 37 and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. The election was made without traverse in the response filed May 8, 2006.

Accordingly, Claims 1-36, 38, and 40-43 are examined herein.

With regard to the interview request, at page 9 of the response, Applicants are directed to MPEP 408.

Applicants' request for rejoinder between product and process claims is noted. However, the product claims are not currently allowable and therefore the process claims will not be rejoined at this time.

Claim Objections

Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 23 is directed to the transgenic mouse of claim 1, wherein the nucleotide sequence of α -synuclein comprises a wild-type coding sequence of α -synuclein. Claim 1, however, is already limited to a

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sequence encoding a wild-type human α -synuclein. Thus, Claim 23 fails to further limit the subject matter of Claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1-36, 38, and 40-42 stand rejected and Claim 43 is rejected under 35 U.S.C. 112, first paragraph, for reasons of record set forth in the Office Action of 8/2/06, because the specification, while being enabling for a transgenic mouse comprising: a first transgenic nucleotide sequence, integrated into the genome of said mouse, comprising a sequence encoding the wild-type human amyloid precursor protein, 751 amino acid isoform (hAPP751), operably linked to a neuron-specific promoter; and a second transgenic nucleotide sequence, integrated into the genome of said mouse, comprising a sequence encoding wild-type human α -synuclein operably linked to a neuron-specific promoter; wherein the first and second transgenic nucleotide sequences are expressed, and wherein said transgenic mouse develops amyloidosis, neurofibrillary tangles, and intraneuronal accumulation of α -synuclein,

does not reasonably provide enablement for the full scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants are reminded that the above-indicated scope of enablement is not meant to suggest specific claim language and that proper support in the as-filed specification for any claim terminology introduced by amendment is always required.

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At pages 10-11 of the response, Applicants assert that the instant amendment is intended to limit the claimed subject matter to the scope acknowledged by the Office to be enabled. However, the claims as presently written are broader than the indicated scope of enablement, particularly in the recitation in Claim 1 of "a wild type or 751 amino acid isoform (hAPP751) human amyloid precursor protein." The scope of enablement indicated in the Office Action of 8/2/06 notes that the first transgenic nucleotide sequence encodes "the wild-type human amyloid precursor protein, 751 amino acid isoform (hAPP751)." Nevertheless, the instant claims cover any wild-type hAPP or a 751 amino acid isoform of hAPP, which would include mutant forms of the 751 amino acid isoform. hAPP751 is the full-length wild-type form of hAPP. It is the longest isoform and the instant specification only provides an enabling disclosure for a transgenic mouse overexpressing the wild-type 751 amino acid isoform of hAPP in combination with the wild-type human α -synuclein. The dependent claims recite many mutant forms of hAPP and α -synuclein, as well as other isoforms of hAPP, but the specification fails to enable this scope, for reasons of record. The claims also recite that the transgenic mouse develops "amyloidosis, neurofibrillary tangles or intraneuronal accumulation of (h) α -synuclein" but the specification does not disclose mice that exhibit one characteristic in the absence of the others. The specification only discloses how to make mice that exhibit all three characteristics together. Claims 42 and 43 are directed to a very broad scope of combination transgenics because the claims do not specify a breeding partner, and therefore the mice of the invention may be bred to any other transgenic mouse to produce combination transgenics that are neither described nor enabled by the instant specification, for reasons of record.

Therefore, the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is indefinite in its recitation of "wherein the h α -synuclein is a mutant or a truncated form of h α -synuclein" because Claim 1, from which Claim 24 depends, is already limited to a wild-type human α -synuclein. Therefore, it cannot be a mutant or truncated form.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Business Center will notify applicants of the resolution of the problem within 5-7 business days.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER